

## REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

Applicants appreciate the courtesies shown to Applicants' representative by Examiner Bouchelle during the October 31, 2008 personal interview. The reasons warranting favorable action discussed during the interview are incorporated into the following remarks and constitute Applicants' separate record of the interview.

As discussed during the interview, entry of the amendments is proper under 37 CFR §1.116 as the amendments: (a) place the application in condition for allowance for the reasons discussed herein; (b) do not raise any new issue requiring further search and/or consideration as the amendments amplify issues previously discussed throughout prosecution; and (c) place the application in better form for appeal, should an appeal be necessary. The amendments are necessary and were not earlier presented because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

Independent Claims 1 and 4 are the only independent claims under consideration. The Office Action rejects independent Claims 1 and 4 under 35 U.S.C. §103(a) over Gross, U.S. Patent No. 4,781,691. The rejection is respectfully traversed.

Independent Claim 1 is directed to an injection needle and independent Claim 4 is directed to a liquid introducing instrument comprising an injection needle. The injection needle comprises a puncture section having a needle point capable of piercing a living body, a proximal end section having outside and inside diameters greater than the puncture section, and a tapered section interconnecting the

puncture section and the proximal end section. The length of the tapered section ranges from 1.5 mm to 10 mm. The total length of the puncture section, the proximal end section and the tapered section to be inserted in the living body ranges from 5 mm to 40 mm. The tapered section possesses an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line parallel to the central axis of the injection needle. The tapered section provides puncture resistance smaller than the puncture section, and a puncture resistance at the puncture section is 7 gf or less.

The Office Action acknowledges that Gross fails to disclose the following features: (1) the length of the tapered section ranges from 1.5 mm to 10 mm; (2) the tapered section possesses an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line parallel to a central axis of the injection needle; (3) the tapered section provides puncture resistance smaller than the puncture section; and (4) a puncture resistance at the puncture section is 7 gf or less. The Office Action takes the position that all of these features would have been obvious to one skilled in the art in view of the disclosure in Gross. Applicants respectfully disagree.

With respect to feature (1), the Office Action takes the position that the claimed lengths would have been obvious because "It is well known in the art to use needles of varying lengths to meet the requirements of the procedure" (see page 5 of the Office Action). As discussed during the interview this statement is insufficient evidence to support the Office Action's conclusion that it would have been obvious to modify the tapered intermediate portion 18 of Gross to have a length ranging from 1.5 mm to 10 mm. The Patent Office's Examination Guidelines for Determining

Obviousness Under 35 U.S.C. §103(a) in view of *KSR International Co. v. Teleflex Inc.* state that the Examiner should clearly articulate why the claimed invention would have been obvious. For example, the Supreme Court in *KSR* held that the Examiner "must [provide] some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007)). In this case, it is not at all apparent why the stated modification would have been obvious to an ordinarily skilled artisan. The Official Action here fails to explain, with articulated reasoning or rational underpinning, why it would have been obvious to modify the tapered intermediate portion 18 of Gross to have a length ranging from 1.5 mm to 10 mm. As discussed during the interview, simply because something could have been modified and a person of ordinary skill was capable of making the modification does not mean it would have been obvious to do so. Thus, there is inadequate evidence supporting the conclusion that it would have been obvious to modify the tapered intermediate portion 18 of Gross to have a length ranging from 1.5 mm to 10 mm, as recited in independent Claims 1 and 4.

With respect to feature (2), the Office Action states that "It is well known that a reduced angle will provide a smaller puncture resistance" (see page 3 of the Office Action). As discussed during the interview, this statement also is insufficient evidence to support the Office Action's conclusion that it would have been obvious to modify the tapered intermediate portion 18 of Gross to possess an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line parallel to a central axis of the needle 10. In particular, there is no articulated reasoning with rational underpinning to support this conclusion of obviousness. Simply because the claimed angle was possible, and a person of ordinary skill was

capable of making the modifying the tapered intermediate portion 18 to have the claimed angle, does not mean it would have been obvious to do so.

As discussed during the interview, should the rejection of Claims 1 and 4 be maintained, the Examiner is kindly asked to provide articulated reasoning with some rational underpinning as to why the specific range of 1.5 mm to 10 mm in length and the specific range of 0.5 degree to 1 degree and 20 minutes would have been obvious modifications to the tapered intermediate portion 18 of Gross' needle 10.

With respect to (3) and (4), the combination of the claimed length and angle of the tapered section recited in Claims 1 and 4 positively influence the puncture resistance of the tapered section relative to the puncture section, and in particular that the resistance is less than 7 gf. This is explained in the specification with respect to Fig. 8, which shows a puncture resistance comparison of a needle having the claimed features and a comparative needle with a tapered section having a length of only 1 mm and a taper angle of 4 degrees, 17 minutes and 21 seconds (see page 22, lines 11-17 and line 22 to page 23, line 4). As shown in Fig. 8, the claimed taper section provides a puncture resistance smaller than the puncture resistance of the puncture section. In the comparative needle, on the other hand, the puncture resistance of the taper section is larger than the puncture resistance of the puncture section. In addition, the puncture resistance at the claimed taper section is well below 7 gf, while the puncture resistance at the taper section of the comparative needle is much greater than 7 gf. Thus, the combination of the claimed length and angle of the tapered section recited in Claims 1 and 4 result in the puncture resistance of the tapered section being lower than the puncture resistance of the puncture section, and in the puncture resistance being less than 7 gf.

Accordingly, simply because it may be "well known in the art to use needles of varying lengths" and "that a reduced angle will provide a smaller puncture resistance", does not necessarily mean that any combination of lengths and angles known in the art would have resulted in the claimed puncture resistance at the taper section.

Gross does not mention that puncture resistance is of concern in configuring the disclosed needle assembly. The observation in the Official Action that Gross inherently discloses a puncture section having a puncture resistance of 7 gf or less is not supported by the record because the Office Action's evidence is insufficient to show that the features contributing to the claimed puncture resistance would have been obvious in view of Gross, as discussed above.

In view of the above, it is respectfully submitted that the combination of features of: (1) the length of the tapered section ranging from 1.5 mm to 10 mm; (2) the tapered section possessing an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line parallel to a central axis of the injection needle; (3) the tapered section providing puncture resistance smaller than the puncture section; and (4) a puncture resistance at the puncture section being 7 gf or less, would not have been obvious to one skilled in the art. Thus, independent Claims 1 and 4 are patentable over Gross. Therefore, withdrawal of the rejection of these claims is respectfully requested.

Claims 3, 5 and 7-18 are patentable over the applied references at least by virtue of their dependence from patentable independent Claim 1. Thus, a detailed discussion of the additional distinguishing features recited in these dependent claims is not set forth at this time.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: November 5, 2008

By:

  
Matthew L. Schneider  
Registration No. 32814

David R. Kemeny  
Registration No. 57241

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620